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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,942	12/06/2001	Guriq Basi	ELN-002	5594
959	7590	01/19/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,942

Applicant(s)

BASI ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41, 62 and 165-206 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41, 62 and 165-206 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41, 62 and 165-206 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/3/02, 7/11/03, 11/29/04
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 11/8/04
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Response and Amendment filed 26 November 2004 has been received and entered in full.
2. The references filed with the Response and Amendment filed 26 November 2004 have been considered by the Examiner.
3. The Supplemental Response and Amendment filed 14 December 2004 has been received and entered in part. The Supplemental Response and Amendment contains a typo on pp. 9 “amiono”. Applicant is invited to supply a replacement Amendment to correct this typo in the response to this Office Action.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

5. The Objection to the Claims as set forth at pp. 3 ¶5 in the previous Office Action (26 May 2004) is hereby *withdrawn* in view of Applicant's amendments (26 November 2004 and 14 December 2004).
6. The Double Patenting rejections as set forth at pp. 3-5 ¶¶6-10 in the previous Office Action (26 May 2004) are *withdrawn* to allow the Examiner to consider Applicant's amendments and amendments (26 November 2004).
7. The Rejection of claims 8, 9, 21, 22, 24, 25, and 32 under 35 U.S.C. §112 ¶2 as set forth at pp. 5-7 ¶¶12-17 in the previous Office Action (26 May 2004) is *withdrawn* in view of Applicant's amendments (26 November 2004 and 14 December 2004).

***Information Disclosure Statement***

8. The information disclosure statement (IDS) filed on 7 October 2002 has been considered. However, References #144, 161, 162, 174, 186, 220, 222, 223, and 304 have been considered but will not be printed because they do not have publication dates.

***Specification — Sequence Rules***

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein. This application discloses sequences in Table 17. Correction is required.

***Statutory Double Patenting***

10. Claims **1-41** and **62** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-41 and 62 of copending Application No. 10/232,030. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

11. Claims **1-41** and **62** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-41 and 62 of copending Application No. 10/388,389. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

12. Applicant's request to withdraw the provisional statutory double patenting rejections in the Response filed 26 November 2004 has been taken into consideration and is not found persuasive. The rejection under 35 U.S.C. for provisional statutory double patenting of the instant applications over Applications 10/232030 and 10/388389 is proper and will remain in effect until Applicant amends the claims of these Applications until they are no longer in conflict or in the event of abandonment.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims **1-41**, **62**, and **165-206** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

Art Unit: 1647

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

14. The invention requires a monoclonal antibody, the 3D6 monoclonal antibody. Since the 3D6 monoclonal antibody is essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The specification does not disclose a repeatable process to obtain the 3D6 monoclonal antibody and it is not apparent if the 3D6 monoclonal antibody are readily available to the public. If the 3D6 monoclonal antibody are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the 3D6 monoclonal antibody.

15. There is no indication in the Specification as to the public availability of the 3D6 antibody. If a deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the 3D6 monoclonal antibody has been deposited under the Budapest Treaty and that the 3D6 monoclonal antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

Art Unit: 1647

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

16. Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

### *Summary*

17. No claims are allowed.

***Conclusion***

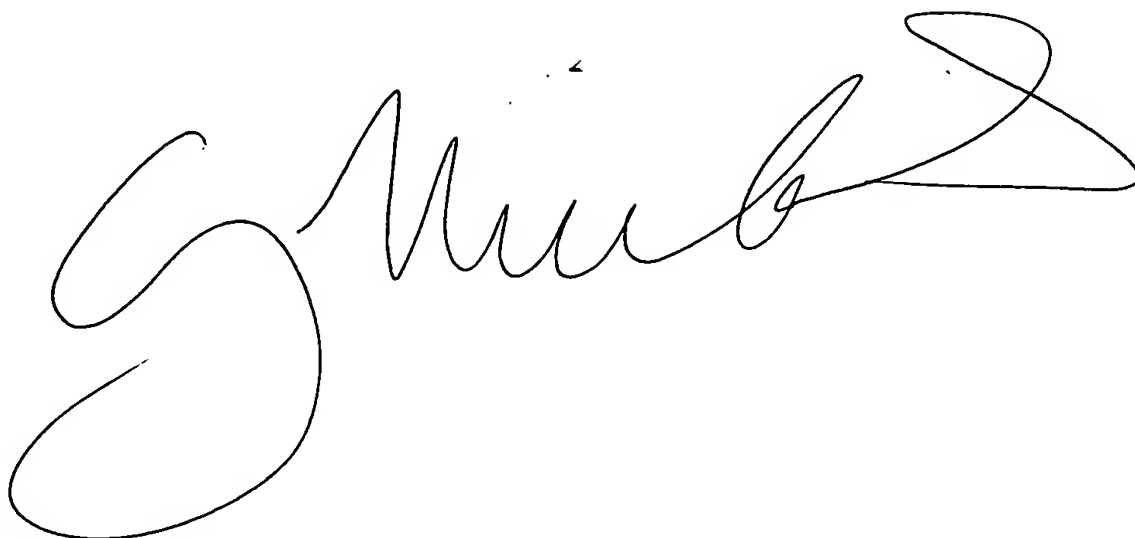
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

January 18, 2005

A large, stylized handwritten signature in black ink, likely belonging to Christopher James Nichols, the examiner mentioned in the text. The signature is fluid and cursive, with a large initial 'C' and 'N'.